UNIVERSITY OF Cincinnati

Human Research Protection Program Policy

NON-COMPLIANCE IN HUMAN SUBJECTS RESEARCH

POLICY

The University of Cincinnati is committed to ensuring that all human research activities conducted under its auspices are conducted safely, ethically, and in full compliance with all applicable laws, regulations, and institutional policies. All allegations of non-compliance with laws, regulations, and university policies in the conduct of human research will be investigated. Appropriate corrective action will be taken in the event there is a determination of non-compliance.

APPLICABILITY

This policy shall apply to all research activities involving human subjects' research conducted at the University.

DEFINITIONS

Non-Compliance: 1) Any deviation from the ethical standards codified in federal, state, and local laws, University rules, research policies, or IRB procedures, or 2) For VA regulated research, noncompliance also includes failure to follow the requirements of VHA handbooks or any unapproved deviations from the approved research protocol. Examples of non-compliance may include but are not limited to:

- Changing study personnel without notifying the IRB;
- Shortening the duration between planned study visits;
- Implementing any changes in study questionnaires without first obtaining IRB approval;
- Failure to obtain IRB approval prior to conducting human subjects research;
- Continuation of research activities after a study has expired;
- Failure to record the date that informed consent was obtained from research subjects enrolled in a study;
- Failure to follow research procedures as outlined in the IRB-approved protocol ;
- Implementation of changes in research procedures or informed consent without prior IRB approval;
- Implementation of a new survey or survey question prior to IRB approval

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Serious Non-Compliance: Any non-compliance that 1) violates the rights and welfare of participants, 2) affects participant safety, 3) increases risk to participants, 4) affects the integrity of the data, or 5) affects the participants' willingness to participate in research.

Examples of **serious non-compliance may** include, but are not limited to:

- Making substantive changes to a previously approved protocol without IRB approval;
- Conduct that adversely affects the integrity or effectiveness of human subjects protections or subjects rights or welfare;
- Conducting non-exempt research that requires direct interaction or interventions with human subjects without first obtaining IRB approval;
- Enrolling subjects who fail to meet the inclusion or exclusion criteria in a protocol that involves greater than minimal risk and that in the opinion of the IRB Chair, designee, or convened IRB places the participant(s) at greater risk;
- Failure to adequately provide informed consent as described in the IRB approved protocol;
- Inadequate supervision in research involving experimental drugs, devices or procedures;
- Failure to follow recommendations made by the IRB to ensure the safety of subjects;
- Failure to report adverse events, unanticipated problems, or proposed protocol changes to the IRB when required to do so, or;
- Serious protocol deviations that place, or have the potential to place, participants at increased risk from the research.

Examples of **serious non-compliance** in research at the VA or conducted by a VA Principal Investigator may include but are not limited to:

- Initiation of VA human subjects research, regardless of level of risk or number of subjects, without written notification from the ACOS for Research that the project may begin;
- Initiation of VA human subjects research, regardless of level of risk or number of subjects, without approval by the IRB;
- Initiation of research interactions or interventions with one or more subjects prior to obtaining required informed consent;
- Conducting research without an approved, signed informed consent document or without a signed Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule authorization for one or more subjects;
- Use of an informed consent document, for one or more subjects, with content not approved by the IRB;

- Failure to report one or more unanticipated SAEs or unanticipated serious problems involving risks to subjects or others as required by the VA Handbook;
- Participation by one or more members of the research team in the conduct of an active protocol without the required credentialing, privileging, or scope of practice, or engaging in activities outside the approved scope of practice, Or;
- Continuation of interactions or interventions with human subjects beyond the specified IRB approval period.

Continuing Non-Compliance: Any non-compliance which continues after the investigator has been notified that corrective action needs to be taken. The pattern of noncompliance is assessed by the number of incidents occurring during the course of the protocol and whether the same noncompliant action was repeated or many different noncompliant events occurred. Continuing non-compliance may also include failure to cooperate with a request from the IRB to resolve an episode of non-compliance.

Examples of **continuing non-compliance** include:

- The occurrence of the same type of deviation (on multiple occasions) from the IRB approved protocol without submission of an amendment to change study procedures;
- Failure to obtain informed consent on more than one subject, or;
- Any pattern of behavior that results in noncompliance.

Examples of **continuing non-compliance** in research at the VA or conducted by a VA Principal Investigator

- Failure to implement IRB-required changes to an on-going protocol within the time period specified by the IRB;
- Deficiencies in informed consent or HIPAA authorization procedures or documentation for ten or more subjects (e.g., outdated informed consent or HIPAA content; lack of required informed consent elements; lack of information required by VA; lack of signature of individual obtaining consent);
- Failure to maintain documentation required by the IRB or by the IRB-approved protocol for ten or more subjects (e.g., inadequate medical record documentation where required;
- Failure to implement remedial actions within the periods specified

The final determination of whether an incident of is “serious or continuing” non-compliance will be made by the IRB as described in Procedure 330.

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Allegation of Non-compliance: A report of noncompliance that represents an unproven assertion. An allegation of serious or continuing noncompliance will be investigated to determine whether it has a basis in fact as described in Human Research Protection Program Procedure Number 330.

Reporting Concerns: Reports of non-compliance may come from many sources including but not limited to an investigator (as a self-report, unanticipated event, protocol deviation); a member of the research team; a study monitor; post approval monitoring program; a sponsor; a research participant; a department chair; or other person not directly involved with the research.

Reports may be submitted in writing or verbally. Verbal reports shall be documented in the IRB's file for the study within 24 hours of receipt.

Compliance hotline: The University maintains an anonymous reporting (compliance) hotline. Information regarding how to use the hotline is provided to all faculty and employees of the University and be posted on the Human Research Protection Program Website. Any person who believes that reporting a violation may result in retaliation may report the violation anonymously through the hotline. Hotline reports which contain allegations of non-compliance in the conduct of research involving human subjects research shall be sent to the Director of UCORI.

Audits and Compliance Reviews: HRPP Auditors will conduct both directed audits and periodic compliance reviews according to Policy VII.01 "Quality Improvement Activities in Human Research Protection."

All allegations of noncompliance will be investigated as described in Procedure 330.

Applicable Regulations and Documents:

45 CFR 46.103(b)(4)(5)
21 CFR 56.108(b)
VHA Handbook 1058.01 May 21, 2010
VHA Handbook 1200.05 October 15, 2010
IRB Procedure 330 "Procedure for Investigating Allegations of Non-compliance"

Adoption Date	Created By:	Date of Revision:	Revised By:	Summary of Revision
11/2006		10/2009	J. Gerlach per AAHRPP	Revise definition of adverse event

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08/2010		08/2010	J. Gerlach	Remove Procedures for Investigating Allegations
10/2010		10/2010	J. Gerlach	Reference additional information form VHA Handbook 1200.05
02/2011		02/2011	J. Gerlach	Add timeframe for reporting loss of PHI for VA studies
05/2011		05/2011	J. Gerlach	VA Office of Research and Development **replaced with** VA Research and Development Committee
01/2014		01/2014	M. Linke	Revised to reflect administrative changes

Date Adopted 1/24/2014 **Signature** signed copy on file